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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/515,014	02/29/2000	Patrick F. Coleman	09197-008810US	1609

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EXAMINER

BROWN, TIMOTHY M

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/515,014	Applicant(s) COLEMAN ET AL.	
	Examiner Tim Brown	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>24 March 2003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Final Office Action is responsive to Applicants' Amendment mailed October 23, 2002. Claims 1-12 are pending. Please note the Examiner of Record for this application has been changed to the present Examiner.

The sequence listing submitted by Applicant has been entered. Applicants' substitute specification has not been entered because it includes pages 24 and 25; the prior Office Action found these pages are new matter. The prior Office Action provided pages 24 and 25 would be entered if Applicants submitted evidence that they were filed with the original application. Applicants responded with a receipt postcard for the election they mailed on January 11, 2003. This receipt postcard, which the Office received on February 4, 2002, is not evidence that pages 24 and 25 were filed on February 9, 2000. Accordingly, the substitute specification is denied entry for including new matter.

Examiner's Note

Claim 13 has been withdrawn from consideration for being drawn to a non-elected species. Claim 13 is not drawn to the species elected by Applicants (i.e. SEQ ID NO: 3) in the election mailed September 25, 2001.

The Examiner maintains the requirement for a new oath or declaration. The prior Office Action required Applicants to submit an oath or declaration because hand-written edits appeared in the original application. Applicants suggest this requirement is moot because these edits do not appear in the substitute specification that has been submitted for entry. However, because the substitute specification has been denied entry, the requirement for a new oath or declaration is maintained.

Claim Rejections - 35 USC § 112, Second Paragraph

The rejection of claims 1-5 and 11 under 35 U.S.C. §112, second paragraph has been withdrawn as being overcome by Applicants' amendment.

The rejection of claim 6 under 35 U.S.C. §112, second paragraph is maintained. Claim 6 was rejected as being vague and indefinite for reciting "substantially all." Applicants argue "substantially all" is clear in light of pages 5 and 12 of the specification. The Examiner respectfully disagrees. Pages 5 and 12 disclose different conjugated markers that can be added to Applicants' modified peptide. These pages do not discuss how the claimed modifications impact the "immunological reactivity" of the peptide. Thus, reciting that the modified polypeptide retains "substantially all" of its prior immunological reactivity renders claim 6 indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 3, 5-9 and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Kang (US Pat. No. 5,858,646).

Applicants' invention is interpreted as comprising an immunoassay that binds and detects HIV antibody using a protein that is at least forty amino acids and has SEQ ID NO: 3 within its sequence. Applicants' immunoassay detects HIV antibody using ELISA, radiolabels, and immunoprecipitation. A carrier protein may be added to the protein to facilitate coupling to a support. Accordingly, Kang teaches the following.

Regarding claims 1 and 12, Kang teaches a method for determining the presence of antibodies to HIV-1 in a body fluid, comprising:

(a) contacting, under conditions which permit immunospecific binding to form a reaction mixture, the body fluid with a composition (Abstract, lines 1-2; and col. 5, lines 28-30) containing at least one polypeptide comprising at least one of the following polypeptide sequences:

BRU124F1X (SEQ ID NO: 3) W-X-Lys-Ile-Gln-Asn-Phe-Arg-Val-Tyr-Tyr-Arg-

Asp-Ser-Asp-Pro-Leu-Trp-Lys-Gly-Pro-Ala-Lys-Leu-Leu-Trp-Lys-Gly-Glu-Gly-Ala-Val-Val-Ile-Gln-Asp-Asn-Ser-Asp-Ile-Lys-Y-Z (Seq. ID No.: 5, amino acids 946-985);

wherein W is either a H of the amino terminal NH₂ group of the polypeptide or an additional amino acid bonded to the amino terminal NH₂ group of the polypeptide, the additional amino acid being selected to facilitate coupling of the polypeptide to a carrier protein or to a support; X is absent or Cys-Gly-Gly; Y is absent or Cys; and Z is OH or NH₂ (Seq. ID No.: 5, amino acids 946-985); and

(b) detecting whether immunospecific binding has occurred between the polypeptide and an antibody component of the body fluid in which an immune complex is formed and in which the detection of the immune complex indicates the presence of antibodies to HIV in the body fluid (col. 6, lines 1-5 and 15-23).

Regarding claim 3, Kang teaches the method according to claim 1 in which the polypeptide is immobilized (col. 5, lines 12-20).

Regarding claim 5, Kang teaches the method of claim 1 in which the composition includes at least one polypeptide selected from a polymerase protein of HIV-1 and one selected from a polymerase of HIV-2 (Abstract, line 4).

Regarding claim 6, Kang teaches the method according to claim 1 in which the polypeptide is modified by the substitution, addition or deletion of amino acid residues so that the modified polypeptide retains substantially all of the immunological reactivity of the unmodified polypeptide (col. 2, lines 12-15).

Regarding claim 7, Kang teaches the method according to claim 6 in which the immunological reactivity is measured by a method selected from the group consisting of radioimmunoprecipitation, immunofluorescence, and enzyme-linked immunosorbent assay (col. 5, line 12).

Regarding claim 8, Kang teaches the method according to claim 1 in which immunospecific binding between the polypeptide or protein and the antibody component of the body fluid is detected by:

(i) removing unbound components from immune complexes formed in the immunoreaction mixture (col. 5, lines 20-21);

(ii) adding a labeled antibody to the immunoreaction mixture, the labeled antibody being capable of immunospecifically binding to a component of the immune complexes and the label providing a detectable signal (col. 5, lines 55-62); and

(iii) determining whether the labeled antibody binds to the immune complexes (col. 6, lines 1-5 and 16-23).

Regarding claim 9, Kang teaches the method according to claim 8 in which the label comprises an enzyme which is detected by the addition of the enzyme substrate (col. 5, lines 55-56).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cosand (US Pat. No. 5,075,211) in view of Kang (US Pat. No. 5,858,646).

Cosand teaches a method for detecting HIV antibody in a body fluid comprising contacting the body fluid with an immunoreactive HIV-1 polymerase protein, and detecting the interaction of antibody and the immunoreactive HIV-1 polymerase protein. Cosand's polymerase protein consists of 30 of the 40 amino acids that make up SEQ ID NO:3. Cosand uses a variety of methods to detect protein/antibody interaction including radiolabeling and fluorescence (col. 6, lines 5 and 60-61). Cosand also provides that its polymerase protein may be linked to a carrier molecule (col. 5, lines 46-54). Cosand does not expressly teach a method for

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detecting HIV by contacting a body fluid with a polymerase protein that comprises all forty amino acids of SEQ ID NO: 3. However, Kang overcomes this deficiency by teaching an immunoassay that detects HIV antibody using a substantial portion of the HIV-pol protein, including SEQ ID NO: 3 (col. 5, lines 12-15). Kang states the advantage of using a larger polymerase protein is that it detects more groups and strains of HIV since smaller, similar proteins may fail to interact with HIV antibody (col. 1, lines 19-25 and 49-52). Therefore, at the time of Applicants' invention, one of ordinary skill in the art would have been motivated to modify Cosand with Kang's larger HIV-pol protein in order to detect a greater population of HIV-infected individuals. Moreover, this combination would have a reasonable expectation success since both Cosand and Kang detect HIV using the same techniques and similar immunoreactive proteins.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Montagnier et al. (US Pat. No. 5,221,610) ("Montagnier") in view of Kang US Pat. No. 5,858,646).

Montagnier teaches a method for detecting HIV antibody in a body fluid comprising contacting the body fluid with a HIV Nef protein, permitting an immunospecific interaction between the Nef protein and anti- Nef antibodies, and detecting the interaction between the Nef protein and anti- Nef antibodies (col. 3, lines 62-67; and col. 4, lines 45-48). Montagnier further teaches detecting the presence of anti- Nef antibody using a variety of methods including immunoprecipitation (col. 16, lines 1-10). Montagnier does not expressly teach a polypeptide comprising SEQ ID NO: 3. However, Kang overcomes this deficiency by disclosing a method for detecting HIV using a protein that includes all forty amino acid sequence of SEQ ID NO: 3. Kang states the advantage of using its HIV-Pol protein as an immunoreactive composition is that

it detects a variety of strains and groups of HIV that would otherwise go undetected by smaller, less reactive, immunoreactive proteins (col. 1, lines 19-25 and 49-52). Therefore, at the time of Applicants' invention, one of ordinary skill in the art would have been motivated to modify Montagnier with Kang's HIV-Pol protein in order to detect a greater population of HIV-infected individuals. Moreover, this combination would have a reasonable expectation success since both Montagnier and Kang are directed to detecting HIV using the similar techniques and immunoreactive proteins.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tim Brown whose telephone number is (571) 272-0773. The examiner can normally be reached on Monday - Friday, 8am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tim Brown
Examiner
Art Unit 1648

tmb


ULRIKE WINKLER, PHD.
PATENT EXAMINER 5/17/04